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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,236	12/12/2001	John Andrew Ryals	PB/5-21215C	4030

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SYNGENTA BIOTECHNOLOGY, INC.
PATENT DEPARTMENT
3054 CORNWALLIS ROAD
P.O. BOX 12257
RESEARCH TRIANGLE PARK, NC 27709-2257

EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,236	RYALS ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10,42,58,59,62 and 68-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10,42,58,59,62 and 68-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 10, 42, 58-59, 62 and 68-93 are pending.

2. It is noted that claims filed 23 February 2004 do not comply with the claim amendment format; namely, all the cancelled claims are not indicated.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The abstract is not descriptive of the instant invention, which is a method for protecting plants by transformation with a NIM1 gene and by applying a microbiocide. A new abstract is required that is clearly indicative of the invention to which the claims are directed. The abstract of the disclosure should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details. The objection is repeated for the reasons of record as set forth in the Office action mailed 27 August 2003. Applicant's arguments filed 23 February 2004 have been fully considered but they are not persuasive.

Applicant urges that the abstract, as amended, is clearly indicative of the claimed invention (response pg 9).

This is not found persuasive because the plants are transformed with one or more SAR genes, but only one gene, the NIM1 gene.

5. The title of the invention is not descriptive of the instant invention, as above. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long. The objection is repeated for the reasons of record as set forth in the Office action mailed 27 August 2003. Applicant's arguments filed 23 February 2004 have been fully considered but they are not persuasive.

Applicant urges that the title, as amended, is clearly indicative of the claimed invention (response pg 9).

This is not found persuasive because more information on the method should be recited, that is what the plant is transformed with and that a microbiocide is applied.

6. The rejection of claim 8 under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,031,153 is obviated by its cancellation.

7. The rejection of claim 93 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicant's amendment of the claim.

Claim Objections

8. Claims 42 and 93 remain objected to because of the following informalities:

In claim 42, "following group" should be replaced with --group consisting of--.

In claim 93, the colon should be deleted.

The objection is repeated for the reasons of record as set forth in the Office action mailed 27 August 2003, as applied to claims 8, 10, 42, 58-59, 62 and 68-93. Applicant's arguments filed 23 February 2004 have been fully considered but they are not persuasive.

Applicant urges that the claims have been amended to address these objections (response pg 10).

This is not found persuasive because they have not so been amended.

Claim Rejections - 35 USC § 112

9. Claims 1, 42, 58-59, 62 and 68-93 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting plants from pathogen attack by applying a microbiocide to a plant transformed with a nucleic acid encoding SEQ ID NO:2, does not reasonably provide enablement for a method of protecting plants from pathogen attack by applying a microbiocide to a plant transformed with a nucleic acid that hybridizes to SEQ ID NO:6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 August 2003. Applicant's arguments filed 23 February 2004 have been fully considered but they are not persuasive.

Applicant urges that claim 1 is drawn to a method of conferring fungal resistance on a plant wherein the method first involves identifying a nucleic acid that encodes a plant immunomodulating protein (response pg 12-13).

This is not found persuasive because the specification fails to provide guidance for the sequence of any nucleic acid that hybridizes to SEQ ID NO:6 other than SEQ ID NO:1.

Applicant urges that knowledge of which amino acids can be changed is not necessary when identifying which proteins are capable of giving rise to immunomodulated plants and that the specification provides guidance for making the claimed nucleic acids (response pg 13).

This is not found persuasive. A recitation for how to find a product is not equivalent to a positive recitation for how to make a product. Furthermore, the specification does not even teach

how to find the nucleic acid - for example, it does not teach where such a nucleic acid would be found.

Applicant urges that the invention can be practiced without undue experimentation; guidance is provided in Examples 20, 23, 31-32, 34 and 77 (response pg 14).

This is not found persuasive. Given the specification's lack of teaching how to make the nucleic acids used in the method, undue trail and error experimentation would be required to practice the claimed invention.

10. Claims 1, 42, 58-59, 62 and 68-93 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 August 2003. Applicant's arguments filed 23 February 2004 have been fully considered but they are not persuasive.

Applicant urges that claim 1 is drawn to a method of conferring fungal resistance on a plant wherein the method first involves identifying a nucleic acid that encodes a plant immunomodulating protein. Applicant submits that this claim is in compliance with the written description requirement because function, synergistic fungal resistance, and structure, hybridization to SEQ ID NO:6, are correlated (response pg 11-12).

This is not found persuasive because Applicant does not describe the structural features (i.e., sequence) of any nucleic acid that hybridizes to SEQ ID NO:6 under the recited low stringency hybridization conditions and that encodes a protein with the recited function.

Furthermore, giving rise to constitutive immunity and being capable of conferring synergistic fungal resistance when used in combination with any of the listed compounds is not a specific recitation of the function of the encoded protein. It is not, for example, the function of the protein in wild-type plants.

Applicant urges that *UC vs Eli Lilly* was discussed extensively in the PTO Interim Guidelines to Written Description and these Guidelines were characterized as being intended primarily for product claims, rather than process or product by process claims (response pg 12).

This is not found persuasive because the written description requirement applies to method claims as well as process claims. See *University of Rochester v. G.D. Searle & Co.*, 69 USPQ2d 1886 (CA FC 2004) states at pg 1887:

> Patent may be held invalid on its face for failure to satisfy written description requirement of 35 U.S.C. §112, even though compliance with that requirement is question of fact; in present case, patent in suit was properly held invalid on summary judgment for failure to satisfy written description requirement, since patent, which is directed to method for inhibiting prostaglandin synthesis in human host using unspecified compound, describes compound's desired function of reducing activity of enzyme "PGHS-2"without adversely affecting "PGHS-1" enzyme activity, but does not identify any compounds that can be used in claimed method of treatment, or even provide evidence that any such compound was known, since claimed method thus cannot be practiced based on specification, since plaintiff did not present evidence that those skilled in art could identify compound based on patent's vague functional description, since patent contains no disclosure of any method for making compound having desired function, and since statute that vests universities, such as plaintiff herein, with patent rights derived from federally-funded research is unrelated to, and unaffected by, legal standards for patentability.

11. Claims 1, 8, 10, 42, 58-59, 62 and 68-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is different from the rejection set forth in the Office action mailed 27 August 2003, as applied to these claims, due to Applicant's amendment. Applicant's arguments filed 23 February 2004 have been fully considered but do not apply to this rejection.

Claim1, line 7, is indefinite in its recitation of "capable of". It is not clear if the protein actually does confer synergistic resistance when used in combination with the recited compounds.

Double Patenting

12. Claims 1, 8, 10, 42, 58-59, 62 and 68-93 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,031,153. The rejection is repeated for the reasons of record as set forth in the Office action mailed 27 August 2003. Applicant's arguments filed 23 February 2004 have been fully considered.

Applicant requests the rejection be held in abeyance until claims have been allowed (response pg 15).

This is granted.

13. Claims 1, 8, 10, 42, 58-59, 62 and 68-93 are free of the prior art, given the failure of the prior art to teach or suggest a method of protecting plants from pathogen attack by applying a microbiocide to a plant transformed with a nucleic acid that hybridizes to SEQ ID NO:6 and that encodes a protein in the signal transduction cascade leading to systemic acquired resistance.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (571) 272-0547.

Anne R. Kubelik, Ph.D.
May 4, 2004

ANNE KUBELIK
PATENT EXAMINER